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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,320	04/01/2004	Hans Binz	PIE1514P0182US	7563
32116 7590 09/24/2007 WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 09/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,320

Applicant(s)

BINZ ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/10/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-29 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-29 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/836,500.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/01/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Preliminary Amendments

- 1) Acknowledgment is made of Applicants' preliminary amendments filed 04/01/04, 12/18/06, 04/12/07 and 07/10/07.

Election

- 2) Acknowledgment is made of Applicants' election filed 12/18/06 in response to the restriction requirement mailed 11/15/06. Applicants have elected invention II, claims 19-29, without traverse. However, Applicants have canceled claims 12-14 and substituted these claims with new claims 19-29.

Status of Claims

- 3) Claims 1-6, 8-11, 15 and 18 have been canceled via the amendment filed 04/01/04.
Claims 7, 12-16 and 17 have been amended via the amendment filed 04/01/04.
Claims 12-14 have been canceled via the amendment filed 07/10/07.
New claims 19-29 have been added via the amendment filed 12/18/06.
Claims 7, 16, 17 and 19-29 are pending.
Claims 7, 16 and 17 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.
Claims 19-29 are under examination. A First Action on the Merits is issued for these claims.

Sequence Listing

- 4) The raw sequence listing submitted in this application has been entered on 11/04/2005.

Information Disclosure Statement

- 5) Acknowledgment is made of Applicant's Information Disclosure Statement filed 04/01/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

- 6) This instant application is a divisional application SN 09/679,750 filed 10/05/00, *now US patent 6,780,420*, which is a continuation of application 08/836,500 filed 08/11/1997, *now US*

patent 6, 197,929, which is a national stage 371 application of the international application PCT/FR95/01463, which claims foreign priority to application 94,13306 filed 07/11/1994 in France.

Specification - Informalities

7) The specification of the instant application is objected to for the following reason:

(A) The first paragraph of the specification as amended via the preliminary amendment filed 04/01/04 does not provide the accurate issued status of the prior applications indicated above in italicized letters under the section 'Priority'. Amendment to the specification is needed.

(B) The use of trademarks has been noted in this application. For example, see page 7 for 'Zwittergent 3-14'; and pages 10 and 11 for 'Tween 20'. Each trademark recitation must be capitalized. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(C) The instant application is informal in the format or arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicants' use.

Content of Specification

- (a) Title of the Invention: See 37 C.F.R 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.
- (b) Cross-References to Related Applications: See 37 C.F.R 1.78 and M.P.E.P § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See M.P.E.P § 310.
- (d) Reference to a "Microfiche Appendix": See 37 C.F.R 1.96(c) and M.P.E.P § 608.05. The total number of microfiche and the total number frames should be specified.
- (e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:

- (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 C.F.R. 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 C.F.R. 1.74.
- (h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 C.F.R. 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not

be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

- (i) Claim or Claims: See 37 C.F.R 1.75 and M.P.E.P § 608.01(m). The claim or claims must commence on separate sheet. (37 C.F.R 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.
- (j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.
- (k) Drawings: See 37 C.F.R 1.81, 1.83-1.85, and M.P.E.P § 608.02.
- (l) Sequence Listing: See 37 C.F.R 1.821-1.825.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 10)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

- 11)** Claims 19-29 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 19 does not recite positive active steps so that the claim sets out and circumscribes particular areas with reasonable degree of precision and particularity and make clear what subject matter the claim encompasses, as well as make clear the subject matter from which others would be precluded. See *Ex parte Erlich*, 3 USPQ2d 1011 (BPAI, 1987). Claim is incomplete because it omits essential steps. There are no steps delineating the claimed process for increasing the immunogenicity of an antigen.

(b) Claims 19-21 include a limitation within parentheses: '(.....)' and raise an indefiniteness issue as to whether or not the recited feature is optional.

(c) Claims 20-29 lack proper antecedent basis in the limitation: 'Process according to claim ...'. It is suggested that Applicants replace the limitation with --The process according to claim--.

(c) Claim 19 is vague and indefinite in the limitation: 'the fragment to ... (SEQ ID NO: ...) of the P40 protein', because it is unclear what exactly does this limitation encompass. What do the numbers 127 and 179 represent is not clear. Furthermore, the limitation 'the' fragment has improper antecedence.

(d) Analogous rejection and criticism apply to claims 20 and 21.

(e) In the last line of claims 19-22, for clarity, it is suggested that Applicants replace the limitation 'sequence ID No. 2' with the limitation --SEQ ID NO: 2--.

(f) The limitation 'K. pneumoniae' in claims 19-21 is inconsistent with the limitation 'Klebsiella pneumoniae' in claim 23. For clarity and to be consistent with the practice in the art, it is suggested that Applicants replace the above-identified limitations with the italicized limitation --*Klebsiella pneumoniae*--.

(g) Claim 19 has redundant antecedence in the limitation 'the said antigen' (see line 2).

(h) Claims 19, 26 and 27 lack proper antecedent basis in the limitation 'or hapten' (see line 2). For proper antecedence, it is suggested that Applicants replace the above-identified limitation with the limitation --or the hapten--.

(i) Analogous rejection and criticism apply to claims 24, 25, 28 and 29 with regard to the limitation 'a hapten' as opposed --the hapten--.

(j) Claim 23 is indefinite and confusing in the limitation 'bacteria of the species *Klebsiella pneumoniae*', because it is unclear what Applicants are trying to encompass via this limitation. Note that the term 'bacteria' is a huge genus whereas *Klebsiella pneumoniae* is a species of the genus *Klebsiella*.

(k) Claim 23 lacks a preceding article before the limitation 'detergent' (see line 4).

(l) Claim 23 has improper antecedent basis in the limitations: 'the supernatant' (see lines 5 and 6); 'the lipopolysaccharides' (see line 4); 'the sediment' (see lines 6 and 7); 'the suspension' (see line 8); 'the fractions' (see line 9); and 'the fraction' (see line 10).

(m) Claim 23 is indefinite in the limitations 'the adjuvant product' (see lines 9 and 11) and 'an adjuvant product' (see lines 12 and 13). Claim 23 depends from claim 19, which includes the recitation of 'an adjuvant', but not 'an adjuvant product'. It is suggested that Applicants delete

the limitation 'product' from lines 9, 11, 12 and 13 and replace the limitation 'an adjuvant product' in lines 12 and 13 of claim 23 with the limitation --the adjuvant--.

(n) Claim 23 is indefinite and improperly broadening in scope in the limitation: 'lipopolysaccharides' (see line 4) and 'lipo-saccharides' (see last line). It is unclear how one differs from the other in terms of scope.

(o) Claim 24 is indefinite in the use of the abbreviated limitation: 'RSV', because it is unclear what is encompassed in this limitation. It is suggested that Applicants replace the abbreviation with the full terminology.

(p) Claim 23 is indefinite, confusing, and improperly broadening in scope in the limitation: 'in order to recover an adjuvant product in the form of protein which is essentially free of lipo-saccharides'. Claim 23 depends from claim 19, wherein the adjuvant recited is limited to SEQ ID NO: 8. However, the limitation in the last two lines of the dependent claim 23 'an adjuvant product in the form of protein' encompasses an adjuvant other than SEQ ID NO: 8.

(q) Claim 24 is vague and indefinite in the recitation 'a fragment', because it is unclear what is encompassed in this recitation. What constitutes a fragment, and how much of the G protein's original structure has to be retained such that the resulting product can be considered as a 'fragment', is not clear. Does a single amino acid residue, or a dipeptide qualify as 'a fragment'?

(r) Claim 23 is indefinite and confusing because it is unclear how the lipopolysaccharide precipitation of step a) is carried out. Are the lipopolysaccharides precipitated from a liquid culture, solid culture of *Klebsiella pneumoniae*, or from an already harvested *Klebsiella pneumoniae* preparation?

(s) Claims 20-29, which depend directly or indirectly from claim 19, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Objection(s)

12) Claim 23 is objected to for missing the limitation --and-- in between steps (d) and (e).

Remarks

13) Claims 19-29 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

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Art Unit: 1645
September 2007


transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

September, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER